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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,970	02/18/2002	James D. Hansen	56512US002	6548

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EXAMINER

BUMGARNER, MELBA N

ART UNIT PAPER NUMBER

3732

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,970

Applicant(s)

HANSEN ET AL.

Examiner

Melba Bumgarner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-17, 19-23 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 15, 20-23 and 28-30 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 16 and 33 is/are rejected.
- 7) ☒ Claim(s) 17, 19, 31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe a pre-strained polymer and a non-prestrained polymer.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wallshein (3,913,228). Wallshein discloses a dental separator 10, the separator dimensioned such that it can be inserted between adjacent teeth, when inserted, the separator exhibits an increase in compressive force, wherein the separator is in the shape of an o-ring (column 3 line 47).
5. Claims 1, 3, 4, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Highgate et al. (4,565,722). Highgate et al. disclose a dental separator, the separator

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dimensioned such that it *can be* inserted between adjacent teeth (figures 1,2), when inserted, the separator exhibits an increase in compressive force, wherein the separator is in the shape of a dog bone (figure 6). As to claims 3 and 4, the separator is a hydrophilic polymer that expands (column 2 line 58). As to claim 13, the separator comprises a pre-strained polymer.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 3, 13, 16, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallstein. Wallstein discloses a separator that shows the limitations as described above; however, they do not show the measure of increase in compressive force. It is believed that the compressive force exerted by the separator increases by greater than about 5%. Wallstein shows a pre-strained elastic material and a shape memory material. It would have been an obvious matter of choice to one of ordinary skill in the art as to the elastic material comprising a polymer. It would have been an obvious matter of choice to one of ordinary skill in the art as to whether the separator also comprises non-prestrained polymer.

8. Claims 2, 5, 6, 8-11, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al. Highgate et al. disclose a separator that shows the limitations as described above; however, they do not show the measure of increase in compressive force, increase in weight and increase in volume. Highgate et al. state that the changes in dimensions may depend upon the amount of liquid absorbed and a dimension may increase by a factor of up to 5. The

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examiner asserts that the claimed properties are present in the separator of Highgate et al. to the same extent even though they are not explicitly stated. It is held to be an obvious matter of choice to one of ordinary skill in the art as to the use of a specific type of known hydrophilic polymer. The specific hydrophilic polymer is not critical to the claimed invention. It would have been an obvious matter of choice to one of ordinary skill in the art as to whether the separator also comprises non-prestrained polymer.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallstein in view of Rawls et al. (5,5,27,181). Wallstein discloses a separator that shows the limitations as described above; however, they do not show a radio-opaque additive. Rawls et al. teach a separator comprising a radio-opaque additive (column 5 line 63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the separator of Wallstein to have radio-opaque additive. One would have been motivated to make such a modification to have a separator that can be viewed on a radiograph in the event of aspiration by a patient in view of Rawls et al.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al. in view of Rawls et al. Highgate et al. disclose a separator that shows the limitations as described above; however, they do not show a radio-opaque additive. Rawls et al. teach a separator comprising a radio-opaque additive (column 5 line 63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the separator of Highgate et al. to have radio-opaque additive. One would have been motivated to make such a modification to have a separator that can be viewed on a radiograph in the event of aspiration by a patient in view of Rawls et al.

Allowable Subject Matter

11. Claims 14, 15, 20-23, and 28-30 allowed.
12. Claims 17, 19, 31, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments filed January 21, 2005 have been fully considered but they are not persuasive. Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection. The prior art show the limitations of the claims.

Response to Amendment

14. The declaration under 37 CFR 1.132 filed January 21, 2005 is insufficient to overcome the rejection of the claims as set forth in the last Office action because: the declaration fails to provide factual evidence pertinent to the rejections. Applicant has only stated that the feature of orthodontic separators are preferred as described in the specification.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 703-305-0740.

The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melba Bumgarner
Primary Examiner